



PATENT
Docket No. 252312007400

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Assistant Commissioner for Patents, Washington, D.C. 20231, on September 18, 2001.

Denise Lade

Denise Lade

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Matthew D. LINNIK and Patricia A.
McNEELY

Serial No.: 09/724,822

Filing Date: November 28, 2000

For: METHODS OF TREATING LUPUS
BASED ON ANTIBODY AFFINITY
AND SCREENING METHODS AND
COMPOSITIONS FOR USE THEREOF

Examiner: To Be Assigned

Group Art Unit: 1646

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**INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of _____ is enclosed.
 - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee. Accordingly, a Petition requesting consideration of the Information Disclosure Statement, an authorization to charge our deposit account, and a Certification under 37 C.F.R. § 1.97(e) are provided herein.

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 is to the best of my knowledge and is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing 252312007400. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: September 7, 2001

Respectfully submitted,

By: Catherine M. Polizzi
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Registration No. 40,130

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Form PTO-1449

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

(Use several sheets if necessary)

Docket Number 252312007400

Application Number 09/724,822

Applicant

Matthew D. LINNIK and Patricia A. McNEELY

Filing Date November 28, 2000

Group Art Unit 1646

Mailing Date September 18, 2001



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U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date if Appropriate
	1.	11/10/1992	5,162,515	Conrad et al.			
	2.	12/07/1993	5,268,454	Barstad et al.			
	3.	01/04/1994	5,276,013	Conrad et al.			
	4.	12/06/1994	5,370,871	Dintzis et al.			
	5.	02/21/1995	5,391,785	Jones et al.			
	6.	09/03/1996	5,552,391	Coutts et al.			
	7.	02/25/1997	5,606,047	Coutts et al.			
	8.	05/27/1997	5,633,395	Coutts et al.			
	9.	03/10/1998	5,726,329	Jones et al.			
	10.	07/28/1998	5,786,512	Jones et al.			
	11.	02/23/1999	5,874,409	Victoria et al.			
	12.	02/08/2000	6,022,544	Dintzis et al.			
	13.	05/09/2000	6,060,056	Coutts et al.			
	14.	03/27/2001	6,207,160 B1	Victoria et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO	
	15.	12/19/1996	WO 96/40197	PCT				
	16.	12/11/1997	WO 97/46251	PCT				
	17.	12/16/1999	WO 99/64595	PCT				
	18.	06/15/2000	WO 00/33887	PCT				
	19.	06/15/2000	WO 00/34231	PCT				
	20.	06/15/2000	WO 00/34296	PCT				
	21.	12/14/2000	WO 00/75105	PCT				

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DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449	Docket Number 252312007400	Application Number 09/724,822
INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)	Applicant Matthew D. LINNIK and Patricia A. McNEELY	
	Filing Date November 28, 2000	Group Art Unit 1646
	Mailing Date September 18, 2001	



OTHER DOCUMENTS

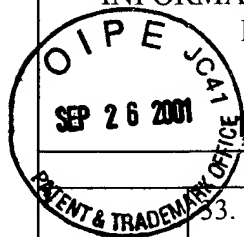
(including author, title, Date, Pertinent Page, Etc.)

Examiner Initials	Ref. No.	Title
	20.	Bootsma, H. et al. (1995). "Prevention of Relapses in Systematic Lupus Erythematosus", <i>Lancet</i> , 345:1595-1599.
	21.	Borel, Y. et al. (1990) "A Novel Technique to Link Either Proteins or Peptides to Gammaglobulin to Construct Tolerogens" <i>J. Immunol. Methods</i> 126:159-168.
	22.	Borel, Y. et al. (1995) "Food Allergens Transformed into Tolerogens" <i>Int. Arch. Allergy Immunol.</i> 107:264-267.
	23.	Borel, Y. et al. (1996) "Parenteral and Oral Administration of Tolerogens: Protein-IgG Conjugates" <i>Ann. N.Y. Acad. Sci.</i> 778:80-87.
	24.	Borg, E. J. et al. (1990). "Measurement of Increases in Anti-Double-Stranded DNA Antibody Levels as a Predictor of Disease Exacerbation in Systemic Lupus Erythematosus", <i>Arthritis Rheumatism</i> . 33:634-643.
	25.	Coutts, S. M. et al. (1996). "Pharmacological Intervention in Antibody Mediated Disease", <i>Lupus</i> 5:158-159.
	26.	Dintzis, R. Z. et al. (1983). "Studies on the Immunogenicity and Tolerogenicity of T-Independent Antigens", <i>The Journal of Immunology</i> 13(5):2196-2203.
	27.	Dintzis, R. Z. et al. (1989). "The Immunogenicity of Soluble Haptenated Polymers is Determined by Molecular Mass and Hapten Valence", <i>The Journal of Immunology</i> 143:1239-1244.
	28.	Dumas, V. et al. (1995). "Induction of Tolerance by Administration of Hapten-Immunoglobulin Conjugates is Associated with Decreased IL-2 and IL-4 Production", <i>Arch. Dermatol. Res.</i> , 287:123-128.
	29.	Foster, M. H. et al. (1993). "Biology of Disease Nephritogenic Autoantibodies in Systematic Lupus Erythematosus: Immunochemical Properties, Mechanisms of Immune Deposition, and Genetic Origins", <i>Laboratory Investigation</i> , 69(5):494-507.
	30.	Jones, D. et al. (1994). "Conjugates of Double -Stranded Oligonucleotides with Poly(ethylene glycol) and Keyhole Limpet Hemocyanin: a Model for Treating Systematic Lupus Erythematosus", <i>Bioconjugate Chemistry</i> 5:390-399.
	31.	Jones, D. et al. (1995). "Immunospecific Reduction of Antioligonucleotide Antibody-Forming Cells with a Tetrakis-Oligonucleotide Conjugate (LJP 394), a Therapeutic Candidate for the Treatment of Lupus Nephritis", <i>J. Med. Chem.</i> 38:2138-2144.
	32.	Morimoto, C. et al. (1982). "A Defect of Immunoregulatory T Cell Subsets in Systematic Lupus Erythematosus Patients Demonstrated with Anti-2H4 Antibody", <i>The Journal of Immunology</i> 139:1960-1965.

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33.	Plunkett, M. L. et al. (1995). "LJP 394: A Novel Clinical Candidate for the Treatment of Lupus Nephritis", <i>Lupus</i> 4:S99.
34.	Seleznick, M. J. et al. (1991). "Variables Associated with Decreased Survival in Systematic Lupus Erythematosus", <i>Seminars in Arthritis and Rheumatism</i> 21:73-80.
35.	Sem, D. S. et al. (1999). "Antibody Affinities and Relative Titers in Polyclonal Population: Surface Plasmon Resonance Analysis of Anti-DNA Antibodies", <i>Archives of Biochemistry and Biophysics</i> 1:372(1):62-68.
36.	Weisman, M. H. et al. (1997). "Reduction in Circulating dsDNA Antibody Titer after Administration of LJP 394", <i>The Journal of Rheumatology</i> 24:314-318.

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